HF 7-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

d15146

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV - 5 1996

VIA FEDERAL EXPRESS

Mr. Robert Mathys Jr.
Mathys Medical Ltd.
Guterstraae 5 CH-2544
Bettlach, Switzerland

Dear Mr. Mathys:

During an inspection of your firm located at Bettlach, Switzerland, on September 25-27, 1996, our Investigator observed the following conditions which were discussed with you at the conclusion of the inspection:

1. Failure to include validation requirements for reproducibility and lack of written documentation concerning study summaries including conclusions for category A machines.

2. Failure to provide adequate facility space designed to prevent mixups in the Q.C. Lab. such as, returned devices not identified as returns; not in any designated returned goods area; and the products were next to finished devices waiting for final inspection.

The above identification of objectionable conditions is not intended to be an all-inclusive list of deficiencies at your facility. The specific deficiencies noted in this letter and in the FDA-483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. Although we have been apprised by the Investigator that you have corrected the spatial deficiency in regard to returned goods and devices waiting for final inspection and the validation requirements deficiencies will be corrected by December 31, 1996, these issues will be evaluated at the time of the next inspection.

Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Ms. Hayden at the above address or at (301) 594-4659 ext. 150 or via FAX (301) 594-4672.

Sincerely yours,

Edgardo Santiago, Chief
Orthopedic, Physical Medicine &
Anesthesiology Devices Branch
Division of Enforcement III
Center for Devices and
Radiological Health